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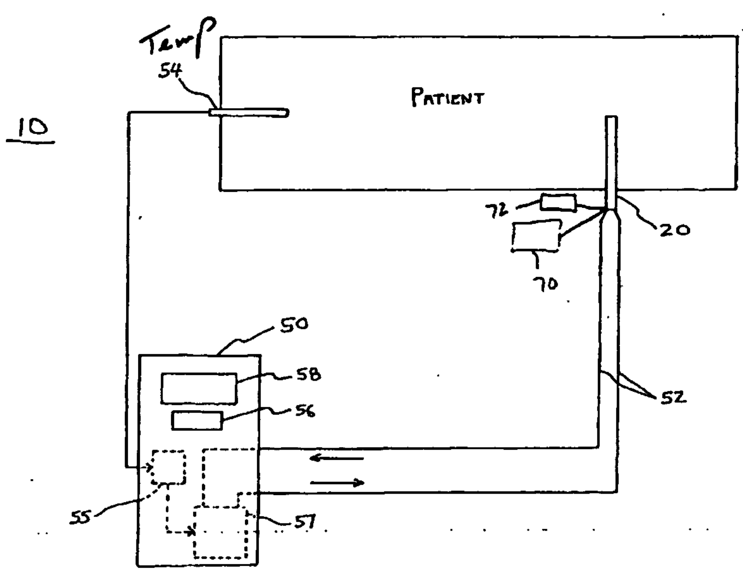
(54) Central venous line catheter having temperature control system

(57) A system for controlling patient temperature uses a central venous line catheter having a heat exchange element. The central venous line catheter is provided with one or more lumens for providing access to the central blood supply of the patient, and with additional lumens for communicating heat exchange fluid to the heat exchange element. Heat exchange fluid temperature is controlled through a feed back loop in which patient temperature is sensed and used to control a temperature control unit comprising a heating device and/or a cooling device in heat exchange relationship with the heat exchange fluid. A tubing set transports the heat exchange fluid between the central venous line and the temperature control unit, with a pump serving to circulate the fluid in a closed fluid circuit in the system.



closed Loop
CNTL

FIG. 1

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Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The invention relates to catheters used for access to the central venous blood supply of a patient.

2. Description of Related Art

[0002] Catheters such as central venous line catheters are typically used in ICU (intensive care unit) patients, particularly in those patients who have suffered a stroke or other brain traumatic event. The central venous line catheters are typically about 8.5 - 12 French in size and consist of a soft, flexible multi-lumen structure extending 8-12 inches. They are usually introduced through the subclavian or jugular vein, and less preferably in the femoral vein of the patient, serving to provide the caretaker with easy and convenient access to the patient's central blood supply via the central venous system. In this manner general access to the central blood supply is gained, enabling for example delivery of drugs, infusion fluids or nutrition, along with the gathering of patient blood for blood gas analysis and the like.

[0003] In many patients, such as ICU patients, fever is a common occurrence. Fever is particularly likely in neuro-ICU patients, and its onset can exacerbate detrimental effects in the brain. Conventional therapies to control fever include treatment with acetaminophen (Tylenol), cooling blankets, ice water bladder lavages, and ice baths. All of these approaches to cooling a patient require excessive time to cool the patient. Moreover, prior methods do not provide for precise control of patient cooling. As recognized herein, to optimize the advantage of cooling a patient, it is important to cool the patient relatively quickly in a controlled fashion.

[0004] Recognizing the above-mentioned deleterious effects of fever in ICU patients and the insufficiencies of present temperature control methods and devices, the present assignee has disclosed, in co-pending patent application Serial Nos. 09/133,813 and 09/063,984, indwelling catheters that can be implanted in the body of a patient to remove heat from the blood supply of the patient. The indwelling catheters of the above-referenced applications are disposed in a heat exchange relationship with the blood supply, and a coolant is circulated through the catheters in a closed loop. These catheters lower the temperature of body tissue and, as mentioned above, can thereby improve the patient's medical outcome.

[0005] As understood by the present invention, the advantages of the above-referenced cooling catheters can be implemented into a central venous catheter configuration. As mentioned above, central venous catheters are commonly used in many ICU patients, including neuro-ICU patients, and with these combined recognitions, the present invention understands that it would be advantageous to provide a central venous catheter with the additional capability of cooling a patient. In doing so, the present invention satisfies the goals both of conventional central venous catheters as well as providing a means for effectively and precisely managing patient temperature in a single device.

BRIEF SUMMARY OF THE INVENTION

[0006] The present invention overcomes the deficiencies of the prior art by providing a central venous line catheter adapted to actively exchange heat with the body of the patient to thereby raise or lower body temperature as required. The central venous line is provided with a heat exchange element disposed in heat exchange relationship with the blood of the patient. The heat exchange element houses a circulating fluid therein, with the fluid being automatically cooled or warmed exteriorly of the patient's body in accordance with a patient temperature feedback scheme.

[0007] By supplementing the known functions of a central venous line catheter with the function of cooling or warming the patient's blood, the present invention takes advantage of existing access to the venous system and a single incision, reducing the risk of additional complications. The access, typically through the subclavian, jugular or femoral veins, is to the central blood supply, via the central venous system, and is therefore particularly expedient, permitting efficient cooling or warming of patient body temperature. The term central venous system generally relates to the portion of the venous system which returns blood to the right heart, including the inferior and superior vena cava. A particular advantage of the invention is that the cooling function is performed efficiently in tandem with a procedure which is known to be likely attended by fever, thus anticipating such fever and facilitating its control. The heat exchange relationship between the system and the central venous system of the patient can be maintained for a prolonged duration - for example, from about one hour to about twenty-nine days.

[0008] The central venous line catheter in accordance with the invention comprises a tubular structure defining a plurality of lumens. At least two of these lumens convey heat exchange fluid to a heat exchange element disposed at a distal, implantable end of the central venous line catheter, while the rest of the lumens serve to provide access to the central blood supply of the patient. The heat exchange element is in fluid communication with a temperature control module via a tubing set which conveys the heat exchange fluid between the components. The temperature control unit, comprising a cooling and/or a heating device, operates in conjunction with a temperature controller to heat or cool the heat exchange fluid depending on a sensed temperature of the patient.

[0009] In a less preferred embodiment, the heat ex-

changer element of the present invention can be made of metal such as steel, and it can assume an appropriate configuration, such as an accordion-like configuration.

[0010] The system of the invention operates to maintain patient temperature at a desired level. Any deviation from the desired level automatically triggers corrective action, such as circulating the cooled heat exchange fluid through the central venous line catheter to contend with the onset of fever. Additionally, the system is equipped with indicators which signal to the caretaker of the patient the sensed deviation, by for example sensing the increased workload of the system, in order to warn of adverse physiological changes besetting the patient.

[0011] The invention thus provides a system for controlling patient temperature using a central venous line catheter having a heat exchange element. The central venous line catheter is provided with one or more lumens for providing access to the central blood supply of the patient, and with additional lumens for communicating heat exchange fluid to the heat exchange element. Heat exchange fluid temperature is controlled through a feed back loop in which patient temperature is sensed and used to control a temperature control unit comprising a heating device and/or a cooling device in heat exchange relationship with the heat exchange fluid. A tubing set transports the heat exchange fluid between the central venous line and the temperature control unit, with a pump serving to circulate the fluid in a closed fluid circuit in the system.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[0012] Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

FIG. 1 is a schematic diagram showing a central venous line catheter temperature control system in accordance with the present invention;
FIG. 2 is a schematic side elevational view of a central venous line catheter in accordance with the invention;
FIG. 3 is a schematic cross-sectional view taken along line 3-3 of FIG. 2;
FIG. 4 is a schematic cross-sectional view of a preferred arrangement of a catheter in accordance with the invention;
FIG. 5 is a schematic sectional view of the distal portion of the central venous line catheter of the invention;
FIG. 6 is a schematic side elevational view of a central venous line catheter in accordance with a second embodiment of the invention;
FIG. 7 is a schematic side elevational view of a central venous line catheter in accordance with a third embodiment of the invention; and
FIG. 8 is a perspective view of one embodiment of the present anchor.

DETAILED DESCRIPTION OF THE INVENTION

[0013] FIG. 1 shows a temperature control system 10 in accordance with the invention. A central venous line catheter 20 providing access to the central blood supply of the patient is disposed in heat exchange relationship with the patient. Central venous line catheter 20 is provided with a circulating heat exchange fluid (not shown) whose temperature is automatically controlled in accordance with a feedback scheme in order to achieve a desired patient target temperature or temperature range. The feedback schemes involves sensing patient temperature using a probe 54 whose output is provided to a temperature controller 55 housed in a temperature control module 50. The temperature controller 55 determines whether the sensed temperature represents a deviation from the desired temperature or range and selectively activates a heat control unit 57 in order to heat or cool the heat exchange fluid depending on the direction of deviation. As described in more detail below, the central venous line catheter 20 is a multi-lumen device, with at least two of the lumens being dedicated to heat exchange fluid flow to and from a heat exchange element of the catheter. The other lumen(s) can have different uses, such as fluid infusion or drug delivery, or guidewire support, depending on the particular application. The preferred number of lumens is 3 to 5, although other numbers are contemplated.

[0014] FIGS. 2-4 show in more detail the central venous line catheter 20, which is a substantially elongate structure of generally cylindrical shape adapted for insertion into the body of a patient, preferably into the subclavian or jugular veins. Central venous line catheter 20 is formed of any known polymer material 23 defining its various lumens 32, 34, 42, 44 and 46. A preferred material is polyurethane, although other materials, such as nylon, polyethylene and PEBAX, can also be used. Considerations in selecting the appropriate material 23 include biocompatibility, flexibility, temperature change compatibility, and resistance to buckling.

[0015] At its distal, implantable end portion 22, catheter 20 is provided with a heat exchange element such as fluid-carrying inflatable balloon 24 that is radially disposed around the width of the catheter. Balloon 24 is disposed in the vicinity of flexible tip 21 and can be formed from a piece of sheet material 38 or extruded tubing formed into a molded balloon of the desired shape and size and then bound or otherwise fixed to the shaft 25 to form a cavity 36. As illustrated, balloon 24 is shown to have a significantly larger diameter than shaft portion 25 of the catheter. For example, it is contemplated that in some applications the diameter of the inflated balloon will be more than three times that of shaft 25. In

one preferred embodiment, the balloon diameter is four millimeters to ten millimeters (4mm-10mm). Preferably, the diameter of the balloon is selected to be no more than 40%-60% of the diameter of a typical vena cava. It is to be appreciated that in some cases it may be desirable to maximize the dimension of the shaft 25 in order to facilitate heat exchange fluid flow. This will also minimize the volume of fluid in the balloon 24 and promote a more rapid heat exchange. It will be further appreciated that myriad balloon shapes can be utilized with the invention, including but not limited to spiral or fluted shapes, as disclosed in the aforementioned co-pending patent applications. The particular shape selected would depend on the application and the desired heat exchange and other characteristics. In one preferred embodiment, the balloon 24 is made of urethane, nylon, or PET and is thin-walled, i.e., the balloon 24 has a wall thickness of less than three mils, and more preferably less than one and one-half mils. Also, the balloon 24 preferably is coated with an antimicrobial substance, as well as an anticlot substance, such as heparin.

[0016] It is to be understood that the balloon 24 can extend the entire length of the portion of the central venous catheter that is intubated in the patient. Typically, this length is about 15 cm. Under such circumstances, the diameter of the balloon need not be larger than the diameter of a conventional central venous catheter, e. g., the diameter of the balloon can be 12 French, 10 French, or even as small as 7.5 French. More broadly, the balloon diameter, when the balloon extends along the entire length of the intubated portion of the catheter, can be 5 - 13 French. In an arrangement where multiple balloons are used as detailed below, these balloons can cover the entire length of the intubated portion of the catheter. That is, two balloons of about 7.5 cm each can be used, or three 5 cm balloons, etc.

[0017] As can be seen more clearly with reference to FIGS. 3 and 4, a pair of lumens 32 and 34 are formed in catheter 20, with lumen 32 serving as an inflow channel supplying balloon 24 with heat exchange fluid which is circulated through the catheter 20, while lumen 34 serves as an outflow channel returning the heat exchange fluid from the balloon 24 to the catheter. The particular heat exchange fluid selected is preferably biocompatible to avoid harm to the patient in the event of inadvertent rupture. Candidate materials include sterile saline water and carbon dioxide gas, although other fluids having suitable viscosity, heat exchange and material compatibility characteristics can also be used. While less desired because it is not biocompatible, freon can alternatively be used.

[0018] Balloon 24 is in fluid communication with lumens 32 and 34 via a plurality of ports such as inlet port 26 and outlet port 28. Heat exchange fluid circulated in catheter 20 passes from lumen 32 into cavity 36 through inlet port 26, then out of cavity 36 to lumen 34 through outlet port 28. While in the cavity 36, the heat exchange fluid, which is remotely cooled outside the central venous line catheter 20, serves to provide a cold temperature fluid on the inner surface of the sheet material 38 which forms the walls of balloon 24. With a body fluid, such as blood, flowing exteriorly of the balloon 24, heat transfer occurs across the sheet material 38, effectively cooling the body of the patient and countering the effects of a fever. To that end, inlet port 26 is positioned distally of outlet port 28.

[0019] Efficient heat transfer is also promoted by specific considerations regarding the cross-sectional shape of the lumens 32 and 34. Specifically, as can be seen from FIG. 3, the lumens 32 and 34 are designed to maximize the volume of fluid flowing therethrough. This is accomplished by providing the lumens with crescent cross-sectional shapes so as to occupy circumferentially a maximum arc length in the catheter 20. This volume maximization, however, may be at the expense of thermal efficiency since the crescent cross-sectional shapes provide greater surface area for undesirable heat exchange with the exterior of the catheter 20 in the shaft portion 25. To obviate this, the preferred cross-sectional shape, shown in FIG. 4, more effectively isolates lumens 32 and 34 from the exterior of catheter 20 by the structural material 37 of the catheter.

[0020] In order to facilitate fluid flow in and out of cavity 36 of balloon 24, outlet port 28 can be made larger than inlet port 26 to reduce the resistance encountered by the heat exchange fluid as it exits the balloon 24. This relative size difference becomes particularly important when multiple balloons are provided in catheter 20 as is contemplated in accordance with an alternate embodiment of the invention. Specifically, although described in terms of a single balloon 24, it will be appreciated that several such balloons can be provided, disposed axially along the length of shaft 25, as shown in FIG. 6. One advantage of a multiple balloon configuration is that the flow and temperature of the heat exchange fluid can be more easily controlled along the entire length of the heat exchange region of the catheter 20. Realizing that the heat exchange fluid will be coolest prior to entering into heat exchange with the blood, and warmest after that heat exchange, one can advantageously control not only the velocity and volume of flow, but also the direction of flow within each of the balloons 24. Another advantage of a multiple balloon design is the ability of the catheter to bend and flex when placed in a curved vasculature.

[0021] Catheter 20 is also provided with two or three lumens 42, 44 and 46 in addition to lumens 32 and 34. Lumens 42, 44 and 46 can serve a multiplicity of functions, including infusion of drugs such as chemotherapy, fluids and nutrition, access to syringes for sampling, and accommodation of various sensors, such as thermistors to monitor the patient, thus generally providing access to the central blood supply as dictated by the particular application. Additionally, central lumen 44 may be made of a different diameter than side lumens 42 and 46 in order to better support a guidewire for instance. The lu-

mens extend substantially the full length of catheter 20, from proximal end portion 27 to distal end portion 22. The number of lumens provided can be varied depending on the particular application.

[0022] It will also be appreciated that the heat exchange element does not necessarily need to be in the form of a balloon such as balloon 24. Rather, arrangements such as an array of flexible hollow fibers through which the heat exchange fluid is circulated can also be used, thus affording greater surface area for heat exchange interaction. Such an arrangement, along with other heat exchange element arrangements which can be used with the invention, is disclosed in the aforementioned co-pending patent application Serial No. 09/133,813, herein incorporated by reference in its entirety. A hollow fiber heat exchange element configuration is shown in FIG. 7. Hollow fibers 58 receive fluid from inner heat exchange fluid lumen 62 and return this fluid to outer heat exchange fluid lumen 64 of catheter 20. Additional lumens such as lumen 66 are also provided to facilitate delivery of fluids and for other uses. An important advantage of a hollow fiber heat exchange element arrangement is that it enables communication between the inner lumens, such as lumen 66, and the blood anywhere along the length of the heat exchange element, via for example port 68. With reference again to FIG. 1, and in cross-reference to FIG. 2, the catheter 20 operates in conjunction with a temperature control module 50. A tubing set 52 (FIG. 1) including coolant inlet and outlet fittings 52a, 52b (FIG. 2) conveys fluid between temperature control module 50 and catheter 20 in a closed fluid circuit through which the fluid is circulated, using known pumping means (not shown) such as for example a diaphragm pump, bladder pump, piston pump, peristaltic pump, etc. It is to be understood that the inlet and outlet fittings 52a, 52b establish pathways of fluid communication from the temperature control unit 57 to the lumens 32, 34, respectively of the catheter 20. A temperature controller 55, which may be a microprocessor having appropriate information storage memory (not shown), is provided in temperature control module 50 and receives patient temperature signals from probe 54. By controlling the input to a temperature control unit 57, which may be a cooling device and/or a heating device in heat exchange relationship with the cooling fluid, temperature controller 55 automatically adjusts the temperature of the heat exchange fluid according to a desired target temperature or temperature range. The target temperature or range can be entered using an input device such as keyboard 56. A display device such as LCD 58 displays various parameters to provide indications of system operation and/or patient condition.

[0023] Preferably, the target temperature is selected to be normal body temperature, and any deviation from this temperature, for example induced by the onset of fever, is sensed by the probe 54 and automatically corrected by the system of the invention. Temperature correction is effected by for example activating temperature control unit 57 of temperature control module 50. In cooling applications, temperature control unit 57 causes cooling of the circulating fluid and ultimately the cooling of the patient's core body temperature, which is monitored by probe 54. When normal temperature is achieved, the temperature control unit 57 can then be automatically switched off or its cooling effect reduced by the temperature controller 55. Suitable temperature control algorithms taking into account performance parameters of system components and system time constants are implemented by temperature controller 55 to effect accurate temperature control. For more expedient temperature control, module 50 may also be provided with a heating device as part of the temperature control unit 57, which heating device can also be automatically activated, using feedback from probe 54, to for example prevent overshooting the desired target temperature or range, or even to induce hyperthermia in some situations. It will be appreciated that probe 54 can be used to provide temperature feedback from any part of the patient's body, rectally for instance, or it can provide temperature information anywhere in the fluid circuit, which information can then be correlated to the patient's core temperature using known parameters such as heat conductivity of different portions of the system and patient data such as weight, height, age, etc. Additionally, more than one probe can be used to provide combinations of readings from the patient and/or from the system to improve accuracy under some circumstances.

[0024] In accordance with the invention, the feedback scheme can be used to maintain desired temperature conditions for a patient. Specifically, the system can be used to control any temperature deviations from an acceptable temperature range, which may be a normothermic range, whereby probe 54 will trigger cooling or heating of the patient's body depending on this sensed deviation from the predetermined range. Moreover, since this deviation is generally indicative of certain physiological activity of which the patient's caretaker should be apprised, the operation of the system can be used as an indication that this physiological activity is taking place. For instance, when the cooling operation of temperature control unit 57 is activated due to a rise in the patient's core body temperature, the system cooling activity, as reflected in the increased workload of the cooling componentry of the system, is then used to indicate to the caretaker, audibly or visibly using an alarm or other status indicator device (not shown) for instance, that the patient's body is attempting to enter a fever state. Appropriate measures can then be taken. Parameters other than workload can be used to provide this indication, such as the slope of the temperature feedback along with the sign of the slope. Alternatively, a direct indication of patient temperature as sensed by the probe 54 can be used. In this manner, use of the system for extended periods of time - for example, from about one hour to about twenty-nine or more days - is facilitat-

ed.

[0025] In cross-reference to FIGS. 1 and 2, in addition to being connected to the temperature control unit 57, the central venous catheter 20 is connected to one or more central venous components 70, 72 (only two venous components shown in FIG. 1 for clarity of disclosure) via respective fittings 74, 76, 78 as appropriate (FIG. 2) to establish communication between the central venous components 70, 72 and selected lumens 42, 44, 46 of the catheter 20. As intended by the present invention, the central venous components 70, 72 can be established by one or more of: drug infusion sources, blood receptacles for receiving blood through the catheter 20, a guide wire, etc.

[0026] Additionally, as best seen in FIG. 2, the catheter 20 includes an anchor configured for affixing the catheter 20 to the patient. More specifically, in one intended embodiment, the anchor is established by a suture fitting 80. The suture fitting 80 can be made integrally with the catheter 20, or it can be made as a separate plastic fitting and surroundingly engaged with the catheter 20. As shown, the suture fitting 80 includes two eyes 82, 84 through which sutures can be positioned and engaged with the patient's skin or with a bandage or tape or other structure that has been fastened to the patient. Alternatively, the present anchor can be established by a piece of tape 86, shown in FIG. 8, that can tape the catheter of the present invention to the patient. Yet again, the present anchor can include another fastening device such as a plate with adhesive surface that can be engaged with the patient, with the plate including structure configured for receiving the catheter of the present invention. As understood herein, an anchor is desirable in a central venous catheter to hold the catheter on the patient, because a central venous catheter typically is intended for prolonged indwelling.

[0027] The above are exemplary modes of carrying out the invention and are not intended to be limiting. It will be apparent to one of ordinary skill in the art that modifications thereto can be made without inventive departure from the spirit and scope of the invention as set forth in the following claims.

Claims

1. A central venous line catheter comprising:

   at least one substantially elongate structure configured for establishing central venous access, said structure having a proximal portion and a distal portion and defining at least a first lumen in communication with the exterior of the structure at said proximal and distal portions;

   at least one heat exchange element extending at least along the distal portion for effecting heat exchange with the central venous system; and

   at least one central venous line catheter anchor engaged with the elongate structure and including structure configured to affix the elongate structure to the patient.

2. A patient temperature control system comprising:

   a central venous line catheter having a proximal portion and a distal portion and defining at least a first lumen in communication with the exterior of the catheter at the proximal and distal portions;

   at least one heat exchange element disposed at least along the distal portion; and

   at least one pump for circulating a heat exchange fluid through the heat exchange element.

3. The patient temperature control system of Claim 2, further comprising a temperature control unit for changing the temperature of the heat exchange fluid.

4. The patient temperature control system of Claim 2 or 3, further comprising at least one probe for sensing patient temperature, the temperature control unit automatically changing the temperature of the heat exchange fluid in accordance with the sensed patient temperature.

5. The patient temperature control system of any of Claims 2 to 4, further comprising a temperature controller for activating the temperature control unit, when patient temperature deviates from a predetermined range.

6. The patient temperature control system of any of Claim 2 to 5, wherein the temperature control unit comprises at least one cooling device for cooling the heat exchange fluid.

7. The patient temperature control system of any of Claims 2 to 6, wherein the temperature control unit comprises at least one heating device for heating the heat exchange fluid.

8. The central venous line catheter of claim 1 or the patient temperature control system of any of Claims 2 to 6, wherein the heat exchange element comprises at least one array of hollow fibres adapted to transport a heat exchange fluid.

9. The central venous line catheter of claim 1 or the patient temperature control system of any of Claims 2 to 6, wherein the heat exchange element comprises at least one balloon adapted to contain a heat

exchange fluid.

10. The central venous line catheter of claim 9 or the patient temperature control system of Claim 9, wherein the central venous line catheter is provided with at least second and third lumens for respectively delivering the heat exchange fluid to and from the balloon.

11. The central venous line catheter of claim 10 or the patient temperature control system of Claim 10, wherein at least the second and third lumens are crescent shaped or multi-faceted shaped in cross-section.

12. The patient temperature control system of Claim 10, further comprising at least one tubing set in fluid communication with the second and third lumens and the temperature control unit, the tubing set delivering fluid between the central venous line catheter and the temperature control unit.

13. The patient temperature control system of any of Claims 2 to 6, further comprising means for providing an indication of patient temperature change.

14. The patient temperature control system of any of Claims 2 to 6, further comprising at least one central venous line catheter anchor engaged with the catheter and including structure configured to affix the catheter to the patient.

15. A patient temperature control system comprising:

a central venous line catheter having at least one heat exchange element disposed at least along a distal portion thereof;

means for sensing the temperature of the patient; and

means for controlling the temperature of the heat exchange element in accordance with the means for sensing the temperature of the patient.

16. A method for controlling patient temperature comprising the acts of:

using a central venous line catheter to gain access to the central venous system of the patient, the central venous line catheter having at least one heat exchange element in heat exchange relationship with the central venous system; and
circulating at least one heat exchange fluid through the heat exchange element.

17. Use of a Central venous line catheter as claimed in Claim 1 in controlling patient temperature.

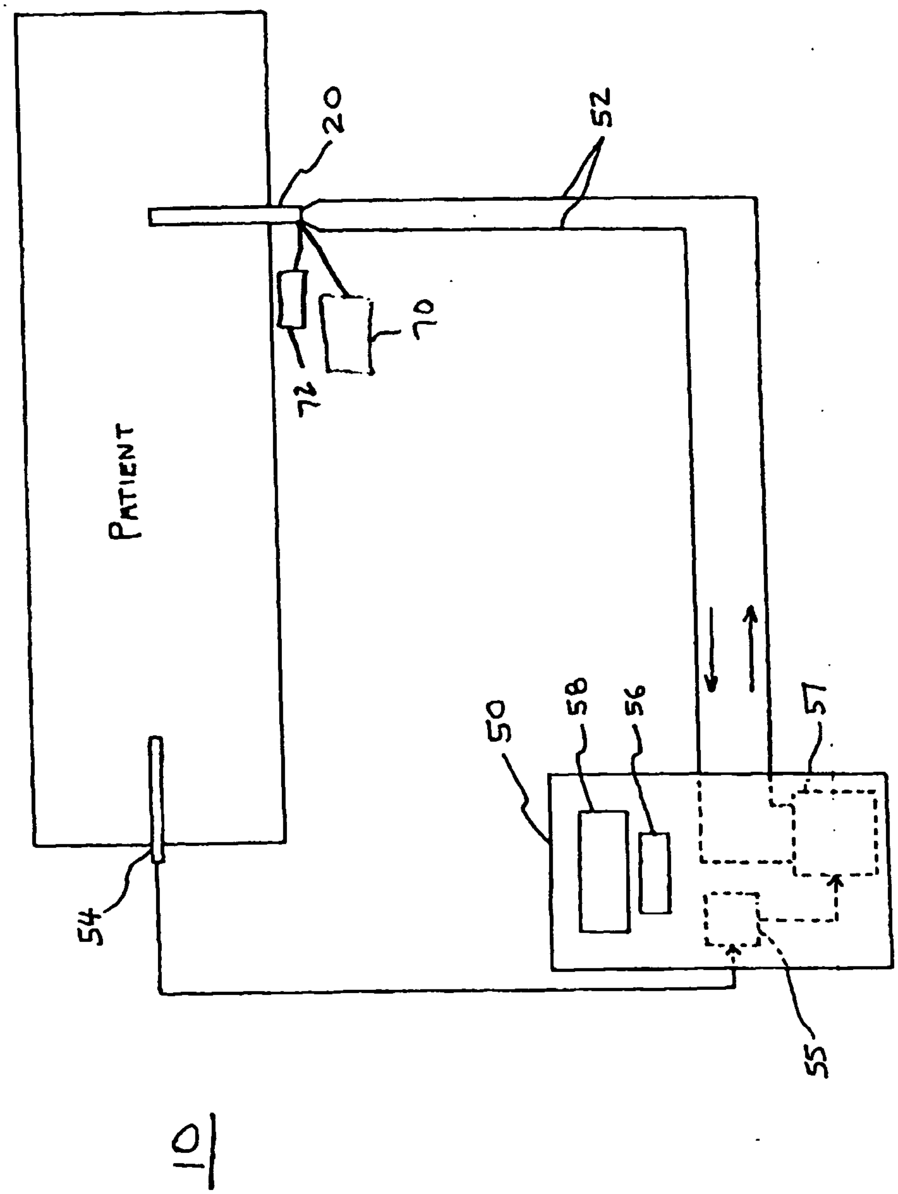

FIG. 1

Fig. 8

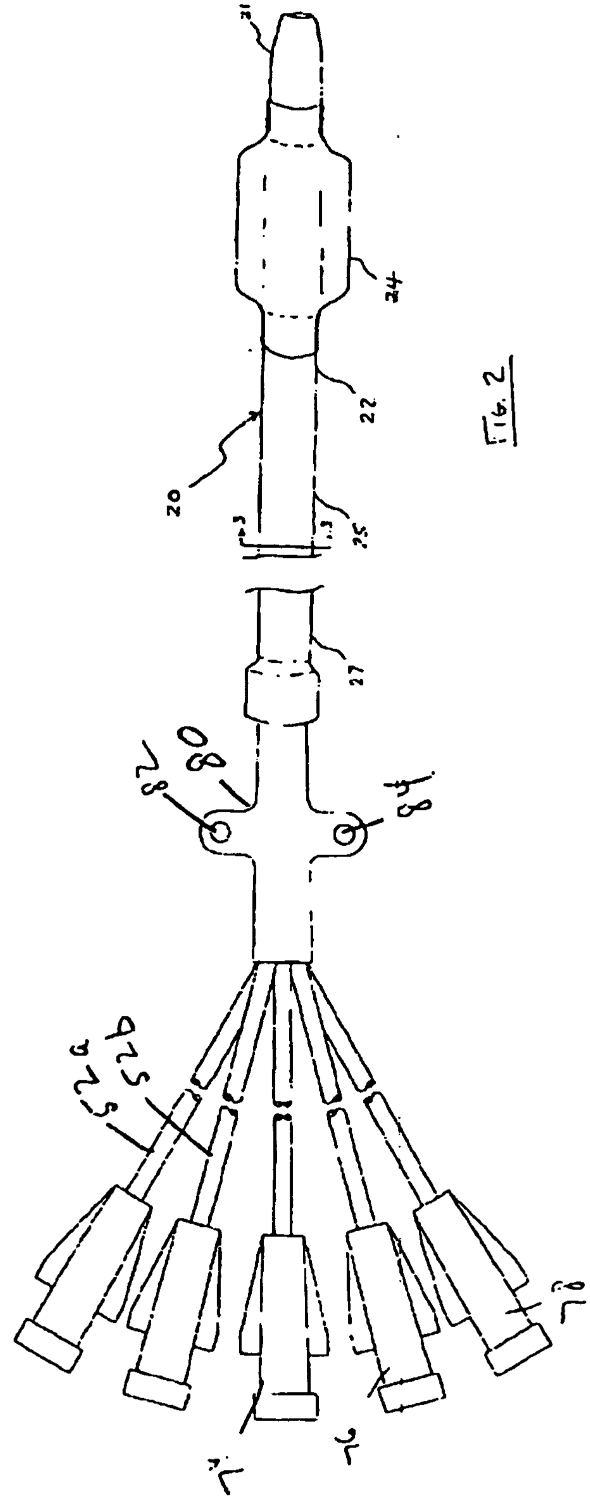

FIG. 2

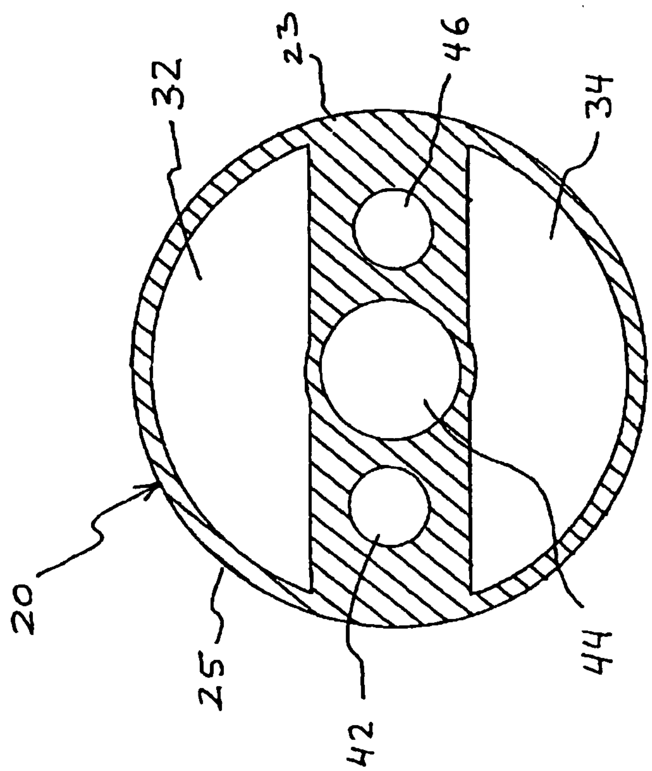

FIG. 3

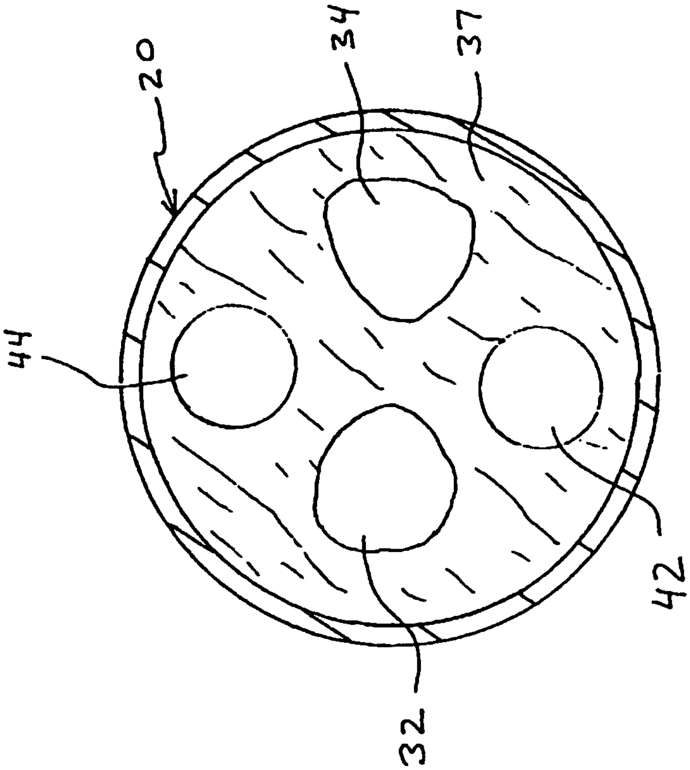

FIG. 4

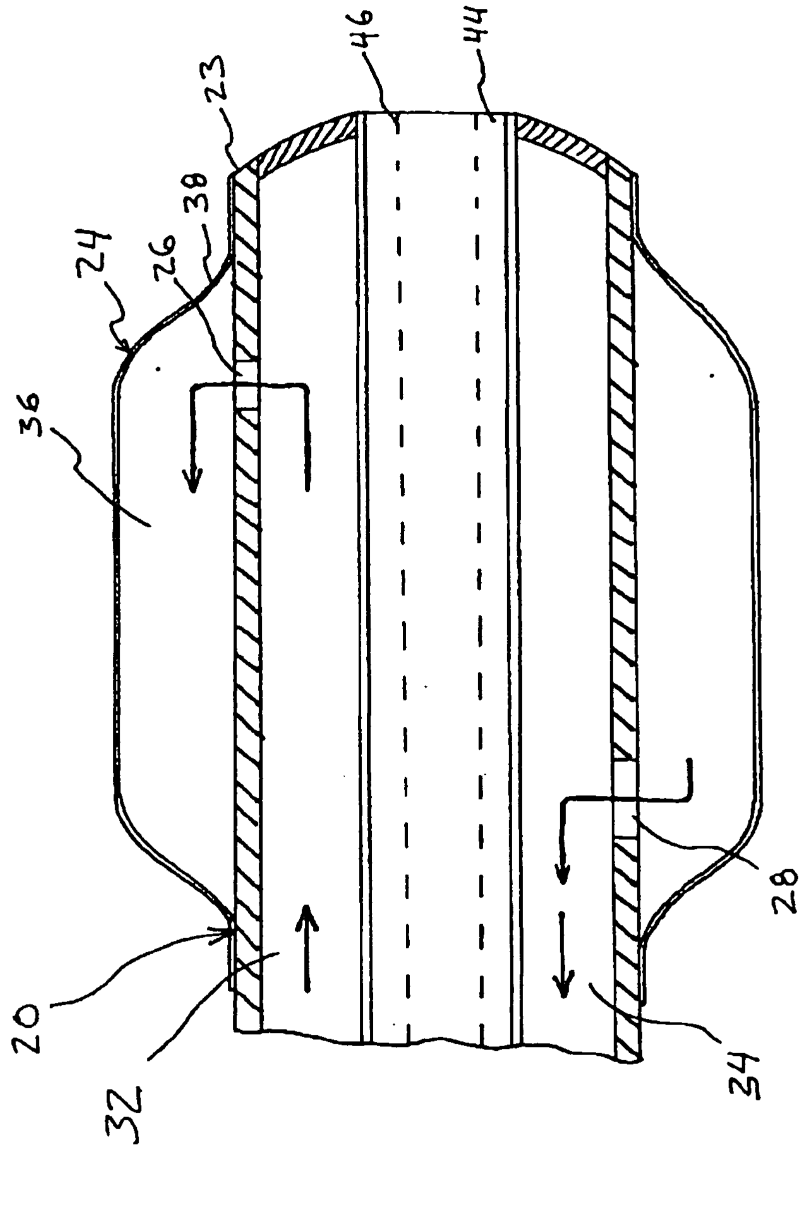

FIG. 5

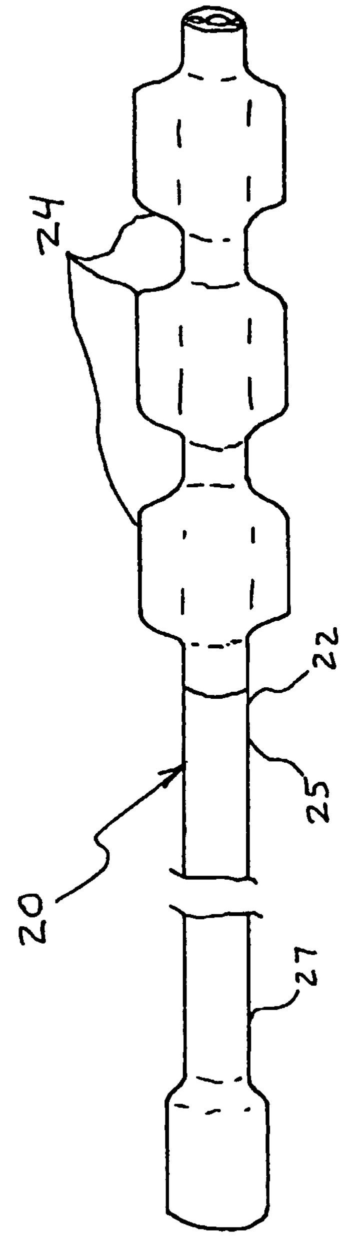

FIG. 6

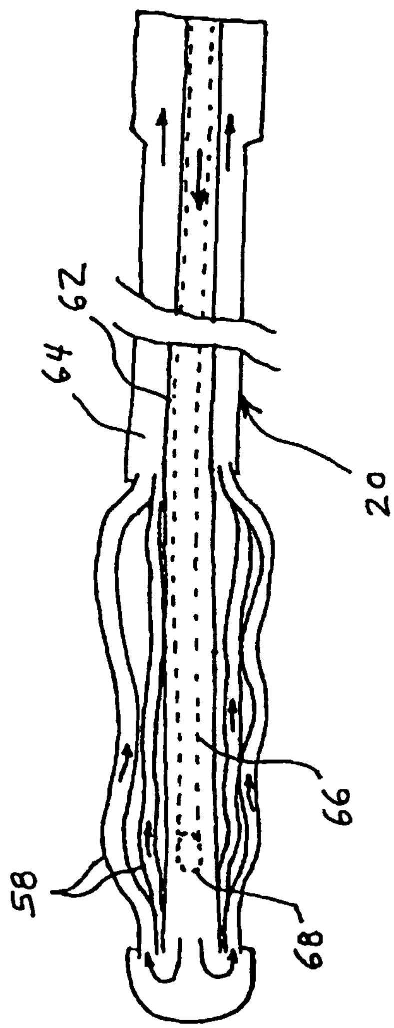

FIG. 7

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number
EP 99 20 1080

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION
X	US 5 549 559 A (ESHEL UZI) 27 August 1996 (1996-08-27) * column 3, line 36 - column 5, line 9; figures * ---	1-3,7,9, 10,14	A61F7/12
X A	US 5 837 003 A (GINSBURG ROBERT) 17 November 1998 (1998-11-17) * column 7, line 13 - column 13, line 6; figures * ---	2-7,9, 10,15 1	
X A	US 5 269 758 A (TAHERI SYDE A) 14 December 1993 (1993-12-14) * column 3, line 7 - column 5, line 16; figures * ---	2,9,10 1,15	
A	US 5 624 392 A (SAAB MARK A) 29 April 1997 (1997-04-29) * abstract; figures * ---	1-3,6,7, 9-11,15	
A	US 5 037 383 A (VASLEF STEVEN N ET AL) 6 August 1991 (1991-08-06) * abstract; figures * ---	2,8	TECHNICAL FIELDS SEARCHED A61F A61M
	-/--		

INCOMPLETE SEARCH

The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.

Claims searched completely :
1-15

Claims searched incompletely :

Claims not searched :
16,17

Reason for the limitation of the search:
Article 52 (4) EPC - Method for treatment of the human or animal body by surgery

Place of search	Date of completion of the search	Examiner
THE HAGUE	25 August 1999	Kousouretas, I

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
A	US 5 151 100 A (ABELE JOHN E ET AL) 29 September 1992 (1992-09-29) * abstract; figures * -----	1,2,15	
			TECHNICAL FIELDS SEARCHED

EPO FORM 1503 03.82 (P04C10)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 99 20 1080

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25-08-1999

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5549559 A	27-08-1996	IL 93842 A	31-10-1995
		EP 0672401 A	20-09-1995
		JP 8080351 A	26-03-1996
		AT 131027 T	15-12-1995
		DE 69115096 D	18-01-1996
		DE 69115096 T	22-08-1996
		DK 449472 T	22-04-1996
		EP 0449472 A	02-10-1991
		ES 2083522 T	16-04-1996
		JP 7067908 A	14-03-1995
		US 5257977 A	02-11-1993
US 5837003 A	17-11-1998	US 5486208 A	23-01-1996
		AU 1691797 A	01-08-1997
		CA 2242362 A	17-07-1997
		EP 0879034 A	25-11-1998
		WO 9725011 A	17-07-1996
US 5269758 A	14-12-1993	NONE	
US 5624392 A	29-04-1997	US 5342301 A	30-08-1994
		US 5411477 A	02-05-1995
		US 5902268 A	11-05-1999
		US 5569195 A	29-10-1996
		AU 7773891 A	10-12-1991
		CA 2082805 A	12-11-1991
		EP 0527969 A	24-02-1995
		WO 9117788 A	28-11-1991
US 5037383 A	06-08-1991	NONE	
US 5151100 A	29-09-1992	US 4955377 A	11-09-1990
		CA 2086667 A	04-01-1992
		EP 0537283 A	21-04-1993
		WO 9200710 A	23-01-1992
		CA 2001628 A,C	28-04-1990
		EP 0561771 A	29-09-1993
		WO 9004365 A	03-05-1990
		US 5496311 A	05-03-1996
		US 5191883 A	09-03-1993
		US 5368591 A	29-11-1994

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82